EXHIBIT B

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November 11, 2019

Via Email

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RE: *In re Valsartan Products Liability Litigation*, No. 1:19-md-02875 (Manufacturing RFPDs)

Counsel:

I write further to the Parties' telephonic meet-and-confer of November 8, 2019, regarding Plaintiffs' Request for the Production of Documents ("RFPDs"). During that call, Defendants requested that Plaintiffs provide examples of documents which are responsive to Plaintiffs' RFPDs related to manufacturing. Without waiving any rights, Plaintiffs provide the below examples of documents, with the hopes that it will expedite production of unobjectionable non-custodial documents related to manufacturing, including all documents referenced in Establishment Inspection Reports. [1]

Plaintiffs' Request

19. Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto;

Examples of Clearly Responsive Documents

For API Manufacturing

- Documents regarding the "scale up" process from "lab scale" to "commercial scale" manufacturing of valsartan API including, but not limited to, documentation of pilot scale

[1] Plaintiffs agreed to provide the enclosed information with the understanding that these identified categories of documents are only meant to be illustrative (not exhaustive) and are being provided in the spirit of continuing an open dialogue between the Parties regarding Plaintiffs' RFPDs. During the November 8, 2019, meet-and-confer, Defendants agreed that Plaintiffs would provide this list without prejudice to Plaintiffs' future ability to request any and all other documents responsive to Plaintiffs' RFPDs that are not identified herein. This list in no way should be construed as narrowing of Plaintiffs RFPDs. As articulated on the meet-and-confer, Plaintiffs do not possess enough information at this point in time to narrow the scope of their manufacturing requests in the manners proposed by Defendants.

batches, documentation of small-scale batches, research and development reports, and product development reports;

- Documents created and/or maintained as part of the deliberation in making a proposed change to the valsartan manufacturing process(es), including, but not limited to, any critical change requests, risk assessments of those proposed change requests, test method validations, and deviation reports associated with those change requests;
- Documents related to the quality assurance measures in place which guide the development of the valsartan manufacturing process including, but not limited to: quality agreements or contracts with any labs used to conduct lab scale studies of valsartan API manufacturing, validation of software and instruments used in testing lab-scale, pilot scale and small scale batches, and validation documents;
- Documents related to deviations in the manufacturing process of valsartan API including, but not limited to, all deviation investigations reports;
- Documents regarding any Out-of-Specification ("OOS") results including, but not limited to, lists of OOS investigations related to Valsartan, all OOS investigation reports for chromatography, OOS investigation reports related to genotoxic impurities, OOS investigations related to instrument error, OOS investigations related to production error, OOS investigations related to lab error, OOS investigations related to unknown peaks;
- Documents regarding all corrective and preventative actions ("CAPAs") initiated over time related to the manufacturing of valsartan API;
- Validation documents provided and/or shown to the FDA during inspections; and
- Standard Operating Procedures ("SOP") and/or management procedures for all steps of the valsartan process development and manufacturing operations including, but not limited to: deviations, stability studies, risk management, change control, change management, returns, reprocessing, chromatography (including handling unknown peaks in chromatography), the keeping and maintaining of reserve samples, API sampling, complaints, returned products and recalls.

For Finished Dose Manufacturing

- Documents regarding all open DMF file documents received from the API manufacturer about their product;
- Supplier samples of API, and all testing conducted therein on the supplier samples;
- Documents containing instructions from the API manufacturer regarding the storage and containment of valsartan API; and
- Documents regarding any onsite or offsite audits by the QA department to evaluate the API factory quality systems, deviations, CAPAs, recalls, warning letters, reprocessing batch reports, annual reports, batch to batch variability documents.

Plaintiffs' Request

20. Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto;

Examples of Responsive Documents

- Lists of equipment used during the manufacture of valsartan API including lists of equipment shared with other processes and lists of dedicated equipment only used in the manufacture of valsartan API;
- Lists of solvents and raw materials used in the manufacturing of valsartan API, and the vendors who provide such materials;
- Lists of materials used in solvent recovery;
- Lists of approved, unapproved, and blocked vendors;
- Raw material receipts;
- Documents regarding to the quality assurance measures in place related to raw materials and/or solvents (and the procurement of those raw materials) and equipment used in the manufacture of valsartan API including, but not limited to: quality agreements or contracts with any vendor used for raw materials, solvents, or solvent recovery, validation of equipment used in valsartan manufacturing, and calibration of measurement devices, change controls to block certain vendors, and CAPA measures put in place to ensure quality oversight of all contractors performing functions that could affect drug quality;
- Documents related to the qualification of any vendors used to source raw materials, solvents, or provide solvent recovery services, including questionnaires and any onsite audits conducted of the vendor's facilities; and
- SOPs and/or management procedures related to raw materials and/or the maintenance of any equipment used in the manufacturing of valsartan API including, but not limited to: cleaning, recovered solvents, raw materials and packaging materials, pest and rodent control, water purification systems, raw material sampling, and vendor selection and approval.

Plaintiffs' Request

21. Produce all documents (including photographs or video) with regard to any testing or inspections of the machines, materials, and substances utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan;

Examples of Responsive Documents

- Photographs of equipment used;
- Documentation about the cleaning procedures used for valsartan API;
- All testing of incoming solvents,
- Certificates of analysis for all raw materials and substances used in the manufacturing of valsartan API provided to the FDA;
- Validation documents regarding recovered solvents; and
- Validation documents regarding other raw materials used in the valsartan API process;
- SOPs and/or management procedures regarding chromatography (including handling unknown peaks in chromatography), OOS results, the keeping and maintaining of reserve samples, API sampling, solvent sampling, and raw material sampling.

Plaintiffs' Request

22. Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your

affiliated entities, including any quality assurance and testing, and any modifications thereto;

Examples of Responsive Documents

- Documents regarding the testing of incoming API including, but not limited to, reference standards, validation documents, test results, and stability studies;
- Documents regarding the storage of valsartan API;
- Validation and/or verification studies conducted when introducing a newly sourced valsartan API into the manufacturing operations;
- Documents regarding the cleaning procedures used to remove active ingredient from the manufacturing chain;
- Documents detailing the OOS results for the raw materials, in-process testing, and finished dose testing for finished dose valsartan products; and
- Documents detailing or listing CAPAs that have been implemented to the finished dose manufacturing process.

Plaintiffs' Request

23. Produce all documents identifying any patented device, machine, or technology utilized in the manufacture or testing of valsartan;

Examples of Responsive Documents

- Documents which identify all machinery used in the manufacture of valsartan API and/or valsartan finished dose;
- Documents which identify any software programs used in chromatography and/or mass spectrometry testing (e.g., Empower); and
- Documents which detail the solvent recovery processes used in the manufacture of valsartan API either by the manufacturer itself or a contract vendor.

Plaintiffs' Request

24. Produce all documents relating to all patents filed by you or employees and/or agents associated with you to any foreign regulatory body regarding any manufacturing processes associated with the creation or manufacturing of valsartan, including all supporting documentation and/or correspondence associated with the filing of those patents;

Examples of Responsive Documents

- Documents provided with the filing of a patent application including, but not limited to, the description of the process (specification), any claims, any abstracts, any drawings or illustrative material provided, and filing receipts.

Plaintiffs' Request

25. Produce documents which evidence the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof;

Examples of Responsive Documents

- Documents sufficient to show any other manufacturers who may have provided valsartan API to Finished Dose Manufacturers (such as, by way of example, Ranbaxy, who previously provided Torrent with a Letter of Authorization for valsartan API);
- Documents sufficient to show all vendors retained for solvent recovery services (such as, by way of example, Lantech Pharmaceuticals who provided recovered solvents to Defendants Aurobindo and Mylan);
- Documents sufficient to show all vendors who provided starting raw materials used in the manufacture of Valsartan (such as, for example, Linhai Pharmaceuticals, who provided Mylan with CMVCH after Mylan ceased sourcing it from Defendant ZHP);
- Raw Material Manufacturer lists; and
- Vendors who provided IT functions related to testing.

Plaintiffs' Request

26. Produce all certificates of analysis or similar documents concerning valsartan, or documents and communications concerning the same;

Examples of Responsive Documents

- Certificates of analysis for recovered solvents procured from third parties and/or outside vendors;
- Certificates of analysis for all catalysts and solvents used in the tetrazole ring formation process;
- Certificates of analysis for valsartan API received by Finished Dose Manufacturers; and
- Certificates of analysis for any raw material, solvent or API provided to the FDA in the course of an investigation.

Plaintiffs' Request

27. Produce complete documentation setting forth (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture/production for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you had or have with regard to potential risks of the use of any solvent utilized including residual or reused solvents;

Examples of Responsive Documents

- Valsartan API batches production records including, but not limited to, all released batches, stability batches, reprocessed batches, and failed batches;
- Elemental impurity risk assessments related to solvents used in the manufacture of valsartan API;
- Hold lists provided to the FDA during inspections; and
- Distribution lists provided to the FDA during inspections.

Plaintiffs' Requests

28. Produce all documents relating to all scientific journal articles submitted to any academic or scientific publication written or drafted in whole, or in part, by your employees or scientists who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including any final version, any drafts, edits, peer reviewed feedback, as well as all communications regarding any possible submission, acceptance or rejection of those journal articles;

29. All documents and communications between you and any third party, outside consultant, university, or individual scientist regarding the manufacturing process associated with the creation of valsartan, including but not limited to the tetrazole ring formation process. These documents should include requests to study the manufacturing process used to create valsartan, exchange of data regarding the manufacturing process used to create valsartan, requests to draft academic journal articles regarding the manufacturing process used to create valsartan, and all documents sufficient to show the payments made and/or contracts between you and those third parties.

With respect to these two requests, Plaintiffs simply note that Defendants are incorrect in their repeated assertions that Defendants, as generic drug manufacturers, do not engage in the practice of drafting and publishing academic journal articles regarding pharmaceutical drugs and/or innovations in drug manufacturing.

Indeed, a cursory search of PubMed shows that Defendants have been prolifically publishing academic articles regarding generic prescription drugs, and the manufacture of API. ZHP, for example, has published 7 academic journal articles since 2017 alone. Mylan likewise has published at least 8 academic articles. APL Research (the research center associated with Aurobindo) has authored over 15 articles in the last few years. Employees from Teva, Torrent and Hetero have also published academic articles. Directly pertinent to Request No. 29, company employees often are co-authors of these articles with academics from research universities or institutions. Additionally, almost all the Defendants (including some Finished Dose Manufacturing Defendants, such as Teva) appeared to have filed patents for the process manufacture of valsartan well before the drug even entered the market. These patent applications appeared to be submitted in conjunction with academics at universities.

Conclusion

Plaintiffs hope the above examples are instructive and will provide Defendants with the information needed to expedite a rolling production of priority manufacturing documents in short order. As discussed during the Parties' meet-and-confer, Plaintiffs identified the above categories and types of documents as a result of their review of Establishment Inspection Reports ("EIRs") documenting FDA inspections of Defendants' manufacturing facilities. Many of these inspections were conducted in the wake of the valsartan recall as a result of the valsartan contamination. The EIRs identified internal manufacturing documents that were reviewed and/or collected by the FDA during inspections of the facilities (many of which directly relate to the manufacturing of valsartan API, or the standard operating procedures in place for the manufacture and testing of valsartan API). Plaintiffs continue to maintain the position articulated in their October 21, 2019, letter that these documents were subject to the Court's Core Discovery Order (D.E. 88) and were required to be produced by Defendants. Consequently, Plaintiffs renew their request that these documents be immediately produced. [2]

Please do not hesitate to contact me if you wish to discuss the above, or to further meet-and-confer with Plaintiffs on the issue of their RFPDs related to manufacturing.

Sincerely,

KANNER & WHITELEY, L.L.C.

By: 

Layne C. Hilton

Cc: Jessica Priselac, Esq. (*via email*) (to distribute to all Defense Counsel)
Plaintiffs' Co-Leads (*via email*)
Plaintiffs' Executive Committee (*via email*)

[2] As Plaintiffs explained during the November 8, 2019, meet-and-confer, production of the documents provided to the FDA during inspections (and consequently cited and identified in the EIRs) will assist Plaintiffs in narrowing the scope of their RFPDs. Until this production of (obviously) important and (clearly) responsive documents occurs, Plaintiffs simply do not have enough information to limit discovery regarding manufacture and testing in the ways Defendants have proposed (*i.e.*, limiting discovery to only one step in the process, or regarding only some small subset of solvents and catalysts and machinery, or limiting discovery to only one type of test).